

REMARKS

Claims 15-16 and 18-39 constitute the pending claims in the present application.

Claims 18, 21, 24, 31, 33, 35, and 36-39 have been amended.

Applicants thank Examiner for indicating the allowability of claims 15 and 16 and for withdrawing several of the rejections from the previous Office Action.

Claim Objections

Claim 22

The objection to claim 22 as being of improper dependent form because it allegedly fails to further limit claim 21 has been maintained. Specifically, it is alleged that “both antibody pairs that bind to both the alpha and beta subunits of FSH would measure total FSH” and that “no structural differences in the antibodies, nor any specific epitopes have been so claimed to distinguish the antibody pairs in such a way that they would not bind total FSH.”

As discussed in the previous Response, it is well-known in the art that antibodies raised or “directed” against the same antigen may in practice bind the antigen in different ways (i.e., with different specificities), especially if the antigen is somehow modified, because the antibodies may recognize different regions of the same antigen. Thus, the fact that both antibody pairs are directed to the combined alpha and beta chains does not require that both antibody pairs would bind to the combined alpha and beta chains in the same way, particularly if the antibodies were mixed with various isoforms of the combined alpha and beta chains (i.e., modified forms of the original antigens against which they were raised). Thus, both pairs do not both necessarily detect total FSH. However, Applicants have amended claim 21 to make it clear that each of the antibody pairs has a different specificity for the combined alpha and beta chains of FSH.

Claim 22 requires that the first antibody pair “detect” total FSH. Because, as noted above, it is possible for two different antibody pairs to be both raised or “directed” against the combination of alpha and beta chains but “bind” the combination of alpha and beta chains with different specificities, and claim 21 now requires this, claim 22 serves to further limit

claim 21 by requiring that the first antibody pair be specific for, i.e. able to “detect” or bind to, total FSH. Accordingly, claim 22 serves to further limit claim 21.

Therefore, the Applicants respectfully request withdrawal of the objection to claim 22.

Claim Rejection – 35 U.S.C. §112¶2 - Indefiniteness

Claims 31-32 have been rejected under 35 U.S.C. §112¶2 as indefinite because the term “give rise to a similar indication” is allegedly not defined by the claims and the specification has been maintained. It is alleged that “what degree of similarity or discernable difference is being claimed . . . is not distinctly claimed.”

Applicants have amended claim 31 to recite “give rise to an identical indication.” Thus, the signals are either identical, or discernably different. Therefore, the Applicants respectfully request withdrawal of the rejection under 35 U.S.C. § U.S.C. §112¶2 for indefiniteness.

Claims 35-36 have been rejected under 35 U.S.C. §112¶2 as indefinite because claim 34, from which these claims depend, allegedly does not set forth the presence of a “labeled specific binding reagent” nor does it define the presence of any zone or zones. Claim 35 has been amended to include a “labeled specific binding reagent” and a “detection zone.” Therefore, the Applicants respectfully request withdrawal of the rejection under 35 U.S.C. § U.S.C. §112¶2 for indefiniteness.

Claim 37 has been rejected under 35 U.S.C. §112¶2 as indefinite because claim 33, from which claim 37 depends, allegedly does not set forth the presence of a “labeled specific binding reagent” nor does it define the presence of any zone or zones. Claim 37 has been amended to include a “labeled specific binding reagent” and a “detection zone.” Therefore, the Applicants respectfully request withdrawal of the rejection under 35 U.S.C. § U.S.C. §112¶2 for indefiniteness.

Claim Objections

Claim 24 has been objected to as not ending in a period. Applicants have amended claim 24 to correct this.

Claims 36 and 37 recite the italicized terms “reagent” and “zone” respectively. Applicants have amended claims 36 and 37 to remove the italics.

Claim Rejection – 35 U.S.C. §102(b) over Alfthan, et al. (1996)

Claims 18, 26, 31 and 38 have been rejected under 35 U.S.C. §102(b) as allegedly anticipated by Alfthan et al. (1996). Applicants have amended claims 18 and 38 to require that each of the two assays use a different antibody pair directed against a different form of the gonadotropin. Alfthan et al. do not teach or suggest two assays using a different antibody pair directed against a different form of the gonadotropin. Accordingly, claim 18, its dependent claims 26 and 31, and claim 38 are not anticipated by Alfthan et al.

Claim Rejection – 35 U.S.C. §102(b) over Anobile (1998)

Claims 18-19 and 38 have been rejected under 35 U.S.C. §102(b) as allegedly anticipated by Anobile et al. (1998). Applicants have amended claims 18 and 38 to require that each of the two assays use a different antibody pair directed against a different form of the gonadotropin. Anobile et al. do not teach or suggest two assays using a different antibody pair directed against a different form of the gonadotropin. Accordingly, claim 18, its dependent claim 19, and claim 38 are not anticipated by Anobile et al.

Claim Rejection – 35 U.S.C. §102(b) over Ulloa-Aguirre, Alfredo et al (1995)

Claims 18-19 have been rejected under 35 U.S.C. §102(b) as allegedly anticipated by Ulloa-Aguirre, Alfredo, et al. (1995). Applicants have amended claims 18 and 38 to require that each of the two assays use a different antibody pair directed against a different form of the gonadotropin. Ulloa-Aguirre, Alfredo, et al. do not teach or suggest two assays using a different antibody pair directed against a different form of the gonadotropin. Accordingly, claim 18, its dependent claim 19, and claim 38 are not anticipated by Ulloa-Aguirre, Alfredo, et al.

Claim Rejection – 35 U.S.C. §102(e) over Birken et al. (U.S. Patent No. 6,521,416)

Claims 18, 26, 31-32 and 38 have been rejected under 35 U.S.C. §102(e) as allegedly anticipated by Birken et al. (U.S. Patent No. 6,521,416). Applicants have amended claims 18 and 38 to require that each of the two assays use a different antibody pair directed against a different form of the gonadotropin. Birken et al. do not teach or suggest two assays using a

different antibody pair directed against a different form of the gonadotropin. Accordingly, claim 18, its dependent claims 26 and 31-32, and claim 38 are not anticipated by Birken et al.

Claim Rejection – 35 U.S.C. §102(b) over O’Daly et al. (U.S. Patent No. 5,391,272)

Claim 39 has been rejected under 35 U.S.C. §102(b) as allegedly anticipated by O’Daly et al. (U.S. Patent No. 5,391,272). Applicants have amended claim 39 to require that the forms are of the same gonadotropin. O’Daly et al. do not teach or suggest that the forms are of the same gonadotropin. Accordingly, claim 39 is not anticipated by O’Daly et al.

Claim Rejections – 35 U.S.C. §103(a)

Claims 18-23, 24, 26-28, 29, 38, 33-37 and 39 have been rejected under 35 U.S.C. §103(a) as allegedly obvious over Berger et al. (1988) in view of EP 0736771 A1 (1995). All of the claims require that the gonadotropin forms detected are used to determine menopausal status. Berger does not disclose that the various FSH forms detected by the disclosed antibody pairs are in any way correlated with menopausal status. EP 0736771 A1 discloses a diagnostic test assembly and method for diagnosing menopausal status. However, it does not teach or suggest how the FSH forms disclosed in Berger would correlate to menopausal status. Accordingly, the references when combined do not teach or suggest the claimed invention. Applicants respectfully request the withdrawal of the rejection for obviousness over Berger et al. (1988) in view of EP 0736771 A1 (1995).

Claims 25 and 30 have been rejected under 35 U.S.C. §103(a) as allegedly obvious over Berger et al. (1988) in view of EP 0736771 A1 (1995) and further in view of Dullien (U.S. Patent No. 6, 174, 665). Claims 25 and 30 ultimately depend from claim 18, which was rejected as allegedly obvious over Berger et al. (1988) in view of EP 0736771 A1 (1995). As discussed above Berger et al. (1988) combined with EP 0736771 A1 (1995) does not teach or suggest the claimed invention. Dullien does not remedy that deficiency. Accordingly, the references when combined do not teach or suggest the claimed invention. Applicants respectfully request the withdrawal of the rejection for obviousness over Berger et al. (1988) in view of EP 0736771 A1 (1995) and further in view of Dullien (U.S. Patent No. 6, 174, 665).

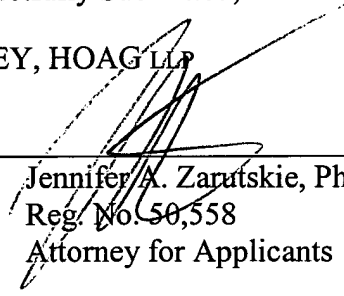
CONCLUSION

Any questions arising from this submission may be directed to the undersigned at (617) 832-1000.

Respectfully Submitted,

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